

REMARKS

In the Office Action mailed November 16, 2009, the Examiner took the following actions:

- (a) rejected claims 1, 6-8, 14-16 and 58 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement;
- (b) rejected claims 1, 6-8, 14-16, 55-58 and 61 under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention;
- (c) rejected claims 1, 6-8, 14, 55-57, and 61 under 35 U.S.C. § 102(b) based on U.S. Patent No. 5,810,721 to Mueller et al. ("Mueller"); and
- (d) rejected claims 15 and 16 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mueller.

By this reply, Applicant amends claims 1, 55, and 58. Claims 1, 6-9, 14-25, 27-36, 55-58, and 61 remain pending in this application. Of the pending claims, claims 9, 17-25, and 27-36 were previously withdrawn. No new matter has been added by this reply.

I. Rejection under 35 U.S.C. § 112, first paragraph

On page 2 of the Office Action, claims 1, 6-8, 14-16, and 58 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully requests withdrawal of this rejection in light of amendments made to independent claims 1 and 58, and in view of the remarks below.

Applicant has amended independent claim 1 to remove the term "substantially." Thus, claim 1 now recites, *inter alia*, "attached continuously around the distal ring." This is fully supported by at least FIGS. 43-46 of Applicant's originally filed drawings. Therefore, Applicant submits that claim 1 complies with the written description

requirement. Claims 6-8 and 14-16 appear to have been rejected due to their dependence from independent claim 1. Thus, Applicant submits that the rejection of claims 6-8 and 14-16 should be withdrawn since claim 1 is fully supported and complies with the written description requirement.

With respect to independent claim 58, page 2 of the Office Action asserts that "a taper toward the longitudinal axis in a plane normal to a plane formed by the distal ring when the distal ring is in the engaged position" is not consistent with FIGS. 43-46 of Applicant's drawings. Claim 58 has been amended, and now recites, *inter alia*, "a taper toward a longitudinal axis of the insertion tool in a plane normal to a plane formed by the distal ring when the distal ring is in the engaged position." In light of the amendment to claim 58, Applicant respectfully submits that any deficiencies of claim 58 have been remedied. To the extent the Examiner believes that claim 58 is still inconsistent with the drawings, Applicant provides FIG. A below. FIG. A is a reproduction of a portion of the tool shown in FIG. 43, with markings added for explanatory purposes.

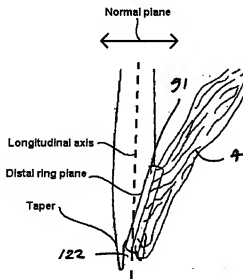


FIG. A

As shown in FIG. A, a distal ring 91 is in an engaged position. Distal ring 91 forms a plane, referred to as a distal ring plane in FIG. A. The distal ring plane is shown from a side view in FIG. A, and thus, has the appearance of a line. A plane normal to the distal ring plane, referred to as a normal plane in FIG. A, is represented by a set of arrows. The normal plane extends in the direction of the arrows. In other words, the normal plane extends along the surface of the page. A longitudinal axis of the tool is also identified in FIG. A, along with a taper. As shown near the bottom of FIG. A, the taper gets closer to the longitudinal axis as the taper approaches a distal tip of the insertion tool. This provides support for stating that the taper is toward the longitudinal axis in claim 58. Moreover, the taper toward the longitudinal axis is in a plane formed by the surface of the page, i.e., the normal plane. Thus, Applicant submits that the recitation of "a taper toward the longitudinal axis in a plane normal to a plane formed by the distal ring when the distal ring is in the engaged position," is consistent with and supported by FIGS. 43-46 of Applicant's originally filed drawings. Therefore claim 58 complies with the written description requirement.

II. Rejection under 35 U.S.C. § 112, second paragraph

On page 3 of the Office Action, claims 1, 6-8, 14-16, 55-58, and 61 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant respectfully requests withdrawal of this rejection.

With respect to independent claim 1, page 3 of the Office Action asserts that the recitation "extends generally in a longitudinal direction with respect to the insertion tool," renders claim 1 vague and indefinite because it is not clear what the "longitudinal direction" is. Applicant respectfully disagrees with this assertion. The phrase

"longitudinal direction" has a clear meaning. For example, "longitudinal" is defined as "placed or running lengthwise," or "of or relating to length or the lengthwise dimension."¹ Thus, the "longitudinal direction" in claim 1 may be defined as a direction running lengthwise with respect to the insertion tool. In response to the Office Action's question (i.e., "Is it a direction along a longitudinal axis of the insertion tool?"), Applicant submits that the longitudinal direction may include a direction along the longitudinal axis of the insertion tool. Since the meaning of "longitudinal direction" is clearly defined, Applicant submits that claim 1 is neither vague nor indefinite.

With respect to independent claim 55, page 3 of the Office Action asserts that the phrase "facing distally away from the insertion tool" is confusing, and provides a suggestion as to how claim 55 should be amended. While Applicant appreciates the suggestion offered, Applicant has taken a different approach, and has amended claim 55 to recite, *inter alia*, "the insertion tool further including a distal end portion including a retractor receiving portion, the retractor receiving portion opening distally away from the insertion tool." The retractor receiving portion opening distally away from the insertion tool is clearly shown in FIGS. 43-46 of Applicant's drawings. Applicant submits that with this amendment, any purported deficiencies of claim 55 have been corrected, and thus, claim 55 is neither vague nor indefinite.

With respect to independent claim 58, page 3 of the Office Action asserts that the recitation "the distal ring extends generally in a longitudinal direction with respect to the insertion tool; and a taper toward the longitudinal axis in a plane normal to a plane

¹ "longitudinal." Merriam-Webster Online Dictionary. 2010. Merriam-Webster Online. 12 March 2010. <<http://www.merriam-webster.com/dictionary/longitudinal>>

formed by the distal ring when the distal ring is in the engaged position," does not clearly recite the structural relationship between the distal ring and the insertion tool. Applicant respectfully disagrees with this assertion. Claim 58 recites, *inter alia*, "the retractor includes a distal portion including a distal ring . . . the insertion tool includes a groove for receiving the distal portion in an engaged position." As such, Applicant submits that the structural relationship between the distal portion (which includes the distal ring) and the insertion tool is clearly recited in claim 58. Moreover, claim 58 has been amended to recite, *inter alia*, "an engaged position where the insertion tool engages the distal ring," as suggested by page 3 of the Office Action.

Page 3 of the Office Action also objects to Applicant's use of the phrase "longitudinal direction" in claim 58. In response, Applicant refers to the remarks above from the discussion of the rejection of claim 1, which explain why the phrase is definite.

Claims 6-8, 14-16, 56, and 57 appear to have been rejected due to their dependence from independent claims 1 and 55. Thus, the rejection of claims 6-8, 14-16, 56, and 57 should be withdrawn since, as outlined above, claims 1, 55, and 58 are definite.

III. Rejection under 35 U.S.C. § 102(b)

On page 4 of the Office Action, claims 1, 6-8, 14, 55-57, and 61 were rejected under 35 U.S.C. § 102(b) based on Mueller. M.P.E.P § 2131 states that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Mueller fails to disclose or suggest each and every element in the claims, whether expressly or inherently, and thus, Mueller does not anticipate the claims.

Amended independent claim 1 recites, *inter alia*, "a retractor having a retracting sleeve . . . and a distal portion including a portion of the retracting sleeve . . . being attached continuously around the distal ring; and an insertion tool . . . including a groove configured to receive and hold the distal portion." Mueller fails to disclose or suggest at least these features of claim 1.

Mueller teaches that "a . . . retractor system 80 comprises retractor 81 and a delivery device including an obturator 88 having a longitudinal channel 89 with inward facing surfaces 90 which restrain the anchor ring therebetween." Mueller, column 10, lines 46-50. Mueller also teaches that "retractor 81 comprises an anchoring ring 82, tabs 84, and an outer ring 86. Tabs 84 have a tissue restraining portion 98 from which tethers 96 extend." Id. at column 10, lines 35-37. But Mueller does not teach a groove configured to receive and hold a distal portion of retractor 81. Rather, Mueller discloses a longitudinal channel 89, which receives the distal portion of retractor 81. See FIG. 10B in Mueller. Thus, Mueller fails to teach or suggest "an insertion tool . . . including a groove configured to receive and hold the distal portion," as recited in amended independent claim 1. For at least this reason, Mueller fails to anticipate claim 1.

Even if longitudinal channel 89 could somehow be interpreted as being a groove, Mueller would still be deficient. This is because Mueller teaches that the distal portion of retractor 81 that is received in longitudinal channel 89 includes tethers 96, not a retracting sleeve. See Mueller, column 10, lines 35-37. Moreover, Mueller fails to disclose that tethers 96 or restraining portions 98 are attached continuously around anchoring ring 82. See id. at Fig. 10C. Thus, Mueller also fails to teach or even

suggest "a portion of the retracting sleeve . . . being attached continuously around the distal ring," as recited in amended independent claim 1. For at least this additional reason, Mueller fails to anticipate claim 1. Claim 1 is therefore allowable over Mueller.

Amended independent claim 55 recites, *inter alia*, "the insertion tool includes a wound opening engaging portion consisting essentially of a monolithic shaft." Mueller fails to disclose or suggest at least this feature of claim 55. Rather, Mueller teaches a wound opening engaging portion formed by two opposed plates. See Mueller at column 10, lines 45-52; and FIG. 10C. Page 4 of the Office Action asserts that a pushrod 95 of Mueller is monolithic. However, Mueller does not teach that pushrod 95 is a wound opening engaging portion of obturator 88. See id. at FIG. 10C. Thus, even if pushrod 95 is monolithic, and Applicant does not agree that it is, Mueller still fails to teach or suggest the above-quoted feature of claim 55.

Claims 6-8, 14, 56, 57, and 61 depend from one of amended independent claims 1 and 55, and are allowable for at least the reasons stated above that claims 1 and 55 are allowable.

IV. Rejection under 35 U.S.C. § 103(a)

Applicant requests withdrawal of the rejection of claims 15 and 16 under 35 U.S.C. § 103(a) over Mueller. As discussed above, Mueller fails to teach or suggest each of the limitations in amended independent claim 1, from which claims 15 and 16 depend. Even if obturator 88 of Mueller could be modified with respect to its dimensions in the manner suggested on page 4 of the Office Action, such a modification would not remedy the deficiencies of Mueller set forth in the discussion of claim 1.

Therefore, claims 15 and 16 are allowable at least for the same reasons that claim 1 is allowable.

V. Response to Arguments

Page 5 of the Office Action asserts that Mueller discloses a monolithic shaft in push rod 95. As noted above in the discussion of the rejection of claim 55 under 35 U.S.C. § 102(b), it is unclear whether Mueller teaches that push rod 95 is monolithic, and even if such a teaching exists, Mueller does not teach that push rod 95 is a wound opening engaging portion. Thus, Mueller does not anticipate the claims.

VI. Rejoinder

Applicant requests that previously withdrawn claims 9, 17-25, and 27-36 be rejoined with the elected claims in this application. Claims 9, 17-25, and 27-36 all depend either directly or indirectly from amended independent claim 1, and thus, are allowable for at least the same reasons that claim 1 is allowable.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant submits that this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge
any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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Dated: May 14, 2010

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